

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant recites a sample application well, a separate sample expression and division means. The specification, "The body 110 further comprises a sample application well 210 (which in figure 2 comprises the sample expression means 300 represented by reference 214), a sample expression means 300 (214 in figure 2), a sample divider 310, for dividing the sample into two portions, and a reservoir 260. The sample application well 210 is in fluid communication with the sample expression means 300. The sample expression means 300 is in fluid communication with the sample divider 310 that directs sample into two or more separate compartments, such as to the reservoir 260 and to the test strip." It is new matter to state a "separate" sample expression and division means when the are physically connected to each other and in fluid communication with each other. Further

the sample application well 210 comprises the sample expression means 300 as seen in figure 7.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 9-38 and 48-55 are rejected under 35 U.S.C. 102(e) as being anticipated by Bachand et al. (USPN 6,489,172).

Bachand discloses a saliva sampling device that comprises an absorbent sample applicator (fig. 5, 17, including a handle), a casing (48), a sample application well 14 which includes an expresser 12 connected to the casing, a sample divider (82) for dividing the sample into a first portion (88) to be tested and a second portion (89) to be stored, a sample reservoir (78) in fluid communication with the sample divider, a test strip (fig. 1, 58,62) with the casing for testing a sample. The absorbent member can be a sponge or foam (col. 3, lines 1-30). The handle of the applicator includes a textured grip 34. The casing further comprises a top portion (near the sample application well) and a bottom portion (fig. 1 near reference 52). The top portion of the casing includes a

reservoir attachment means (fig. 3, col. 4, lines 13-16). The reservoir includes a tamper evident closure cap 81 for sealing the confirmation container 78 after it has been removed from the platform 48 which is made of plastic material. The top portion further comprises a sample application well base (12) and further comprises the sample divider which is in fluid communication with the reservoir and at least one test strip. The top portion comprises an aperture (60) for viewing the test strip. The test strip is supported in a space defined by the interior surface of the top portion and the interior surfaces of the bottom portions. The sample application well further comprises an expressor for expressing the sample from the sample applicator upon the absorbent member being manually pressed into the expressor (col. 3, lines 1-30). Regarding the amendment to claim 1 requiring the top member and a bottom member being removably coupled to one another, the casing comprises a top portion (near the sample application well) and a bottom portion (fig. 1 near reference 52) and also seen in figure 3 (top 42 and bottom 52). The Examiner states that until the Applicant positively recites a structure that provides the top member and bottom member structures to be removably coupled to each other (i.e. retaining clips or pins) then the Bachand is structurally capable of the top and bottom members being removably coupled to each other because if a large force was applied to the top and bottom members they would separate from each other because they are in fact two separate pieces when the device is being put together so as to be able to place the test strip in the well for testing. Regarding the recent amendments to claims 37 and 38 requiring both a sample application well and an expressor, the Examiner points to figure 3 which shows a sample application well 14

which includes an expresser 12 connected to the casing, a sample divider (82) for dividing the sample into a first portion (88) to be tested and a second portion (89) to be stored. The sample application well, sample expression and division means are in the same structural configuration as the instant claims.

Regarding claim 1, this claim includes intended use limitations (i.e. configured to), which do not further delineate the structure of the claimed apparatus from that of the prior art. Since these claims are drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. These recited intended use limitations are accorded no patentable weight to an apparatus. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Response to Arguments

Applicant's arguments filed 10/8/09 have been fully considered but they are not persuasive. The Examiner disagrees with the Applicant's interpretation of "separate" as it applies to claims 37 and 38. Separate as define by Merriam Webster "adjective" 1a,: set or kept apart: detached. By this definition the sample expression and division means have to be detached physically. This is the cause of the new matter rejection because nowhere in the applicant's disclosure is the sample expression and division means physically separate or in a detached space in relation to each other.

Applicant argues, "Applicants contend that Bachand does not anticipate the rejected claims because Bachand does not teach a casing having a top member and a bottom member, wherein the top and bottom members are removably coupled to one another. Bachand does not teach this element because at most Banchand discloses a housing and at no point in time does Bachand teach that the housing is composed of two members capable of being removably coupled to one another." Regarding the amendment to claim 1 requiring the top member and a bottom member being removably coupled to one another, the casing comprises a top portion (near the sample application well) and a bottom portion (fig. 1 near reference 52) and also seen in figure 3 (top 42 and bottom 52). The Examiner states that until the Applicant positively recites a structure that provides the top member and bottom member structures to be removably coupled to each other (i.e. retaining clips or pins) then the Bachand is structurally capable of the top and bottom members being removably coupled to each other because if a large force was applied to the top and bottom members they would

separate from each other because they are in fact two separate pieces when the device is being put together so as to be able to place the test strip in the well for testing.

Applicant argues, "With respect to claims 23 and 31, each of these claims have been amended to clarify that the device includes both a sample application well and an expressor. The Office has not shown where in Banchand a device is taught which device includes both a sample application well and an expressor. Accordingly, Banchand does not teach all the elements of the rejected claims and therefore does not anticipate the claimed invention." The Examiner assumes the Applicant is arguing claims 37 and 38 since these claims require a sample application well and an expressor means. As seen in the new matter rejection, it is new matter to state a "separate" sample expression and division means when they are physically connected to each other and in fluid communication with each other. Further the sample application well 210 comprises the sample expression means 300 as seen in figure 7. Further in the specification, The body 110 further comprises a sample application well 210 (which in figure 2 comprises the sample expression means 300 represented by reference 214), a sample expression means 300 (214 in figure 2), a sample divider 310, for dividing the sample into two portions, and a reservoir 260. The sample application well 210 is in fluid communication with the sample expression means 300. The sample expression means 300 is in fluid communication with the sample divider 310 that directs sample into two or more separate compartments, such as to the reservoir 260 and to the test strip. The sample application well contains the expressor means.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAM P. SIEFKE whose telephone number is (571)272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel P Siefke/
Primary Examiner, Art Unit 1797